



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-1238]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "US Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications," also commonly known as a "TB Follow-Up Worksheet" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on 03/09/2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

The US Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications (OMB Control No. 0920-1238, Exp. 06/30/2021) - Reinstatement with Change - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Global Migration and Quarantine (DGMQ) collaborated with the Division of TB Elimination (DTBE) to revise the proposed worksheet to capture follow-up medical examination information after a person with tuberculosis classification has arrived in the US. The overseas medical examination determines whether the applicant has an inadmissible condition of public health significance (a Class A condition) or has a health-related condition that is admissible, but might require extensive medical treatment or follow-up (a Class B condition), such as treated tuberculosis. Applicants with Class A (inadmissible) conditions can only enter the United States if they are granted a waiver. Applicants who have Class A conditions include those who; 1) have a communicable disease of public health significance, 2) do not have documentation of having received vaccinations against vaccine-preventable diseases, 3) have a physical or mental disorder with associated harmful behavior, or 4) abuse, or are addicted to drugs (42 USC

252, 8 USC 1182, and 8 USC 1222 provide for the physical and mental examination of applicants in accordance with regulations prescribed by the HHS Secretary). CDC highly recommends that persons with overseas class A or B tuberculosis receive domestic follow-up medical examination information to prevent new transmission of tuberculosis. This is the primary rationale for collecting domestic tuberculosis follow-up information.

The US foreign-born population continuously had the highest incidence of tuberculosis compared to the US non-foreign-born population. According to CDC, the 2019 TB case rate was 14.2 per 100,000 for foreign-born persons compared to 0.9 per 100,000 for US-born persons. The proportion of TB cases occurring in the foreign-born population was found to be approximately 70.9% of the national case total. CDC strongly recommends US-bound immigrants and refugees with class A or B tuberculosis to receive follow-up examinations for tuberculosis in the US.

The purpose of this data collection is to methodically gather tuberculosis follow-up outcome data to monitor and track US-bound persons with overseas class A and B tuberculosis to assist in the national effort to prevent new transmission of tuberculosis. To accurately determine recent US arrivals receiving domestic follow-up medical examinations, US health departments will provide domestic follow-up outcome information to CDC by completing The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications, also commonly known as the TB Follow-Up

Worksheet. Without this data, DGMQ will not have a method of tracking and monitoring newly-arrived persons with overseas class A or B tuberculosis. DGMQ will use information reported on the TB Follow-Up Worksheet to ensure that tuberculosis programs are effectively tracking newly-arrived persons and coordinating follow-up medical examinations with state and local clinicians in the US.

Since the previous approval of the "US Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications" data collection instrument in 2018, there have been changes made in the data collection instrument to clarify wording, add additional options for respondents to select, and enhance data collection quality. There are also clarifications made in the "Purpose and Use of Information Collection" in Supporting Statement A to further clarify information what the data collection instrument collects. In the "Respondent Universe and Sampling Methods" section of Supporting Statement B, there are clarifications made to explain how respondents gain access to and use the Electronic Disease Notification (EDN) system and the data collection instrument. There is an increase from 550 respondents to 1548 respondents due to the increase in the number of individuals throughout the United States requesting access to the EDN system to access medical records for U.S. arrivals, and complete the EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications for U.S. arrivals

with TB classifications. There is no change to the burden per respondent to complete a follow-up form.

Several indicators will be calculated to measure domestic tuberculosis program performance, including the percentage of aliens with class B tuberculosis with complete US medical examinations. This program performance monitoring activity will be ongoing throughout the year. State and local health departments will voluntarily report evaluation outcome findings on a continuous basis once evaluation results for an individual becomes available.

Data collected by DGMQ will be used to help evaluate the efficacy and efficiency of overseas tuberculosis diagnoses, treatments, and prevention activities along with panel physician performance. Currently, DGMQ does not have an effective method of determining the accuracy of chest x-rays read overseas and the aptness of overseas treatment for tuberculosis. This data will provide DGMQ with a method of evaluating panel physician performance and overseas treatment and prevention activities. The proposed TB Follow-Up Worksheet contains sections that allow US physicians to review overseas chest x-rays and treatment and indicate any concerns or errors. A negative consequence of not collecting this information is that DGMQ will not be able to efficiently analyze data to determine which panel physicians have the most inaccuracies. Plans for formal evaluations of US panel physicians are contingent upon the approval of the TB Follow-Up Worksheet.

If technical instructions for tuberculosis diagnosis and treatment are followed properly overseas, persons with overseas classification B tuberculosis should not have tuberculosis disease during their US follow-up examinations. The form will help DGMQ understand what factors may contribute to a domestic diagnosis of tuberculosis. The TB Follow-up Worksheet contains a section that collects patient diagnoses and treatment recommendations. Without this information, DGMQ staff will not be able to accurately identify and resolve factors that contribute to tuberculosis disease. This form of monitoring is ongoing and will occur with every instance an alien is diagnosed with tuberculosis disease during follow-up examinations.

There are no costs to the respondents other than their time. The total estimated annual burden are 2,322 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
EDN data entry staff at state and local health	US Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with	1,548	3	30/60

departments	Overseas Tuberculosis Classifications			
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